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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,791	12/20/2001	James W. Clark	KCX-391(16284)	9606
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DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER BOYD, JENNIFER A	
			ART UNIT	PAPER NUMBER
			1771	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/027,791	<b>Applicant(s)</b> CLARK ET AL.	
	<b>Examiner</b> Jennifer A. Boyd	<b>Art Unit</b> 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27 - 38, 50 - 51, 53 - 54 and 56 - 81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 - 38, 50 - 51, 53 - 54 and 56 - 81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2005 has been entered. The Applicant's Amendments and Accompanying Remarks, filed September 2, 2005, have been entered and have been carefully considered. Claims 27, 35 and 37 are amended, claims 1 – 26, 39 – 49, 52 and 55 are cancelled, claims 56 – 81 are added and claims 27 – 38, 50 – 51, 53 – 54 and 56 – 81 are pending. In view of Applicant's amendments, the Examiner withdraws the rejection over Dodd as set forth in the previous Office Action. Despite these advances, the invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102/103***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 27 – 28, 30 – 38, 50 – 51, 53 – 54, 57 – 68 and 70– 81 are rejected under 35

U.S.C. 102(a)(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lunsman et al. (US 2002/0031486).

Lunsman is directed to an antimicrobial cleansing composition and wipe (Title).

As to claims 27 and 35, Lunsman teaches a wipe comprising an effective amount of at least one water soluble or dispersible antimicrobial agent and at least one non-ionic surfactant (page 1, [0009]). Lunsman teaches that the antimicrobial agent can comprise benzalkonium chloride at a concentration from about 0.01 to about 5 weight percent and more preferably from about 0.1 to about 0.4 weight percent based on the total weight of the composition (page 2, [0014]). The composition additionally contains a non-ionic surfactant comprising about 0.1 to 10% by weight and preferably 0.1 to 1% by weight of the composition (page 3, [0020]). The Examiner equates the benzalkonium chloride to Applicant's "benzalkonium halide" and the non-ionic surfactant to Applicant's "at least one non-ionic surfactant". Lunsman teaches that the wipe is impregnated with the composition and the wipe contains about 50 to 600 weight percent of the composition based on the dry weight of the wipe (page 2, [0017]). The wipe may comprise a non-woven substrate (page 3, [0030]). It should be noted that the limitation of "during use of the wiper in food service applications" is considered to be an intended use limitation and is given no patentable weight. The prior art meets the structural and/or chemical limitations set forth and there is nothing on record to evidence that the prior art product could not function in the desired capacity. The burden is shifted upon the Applicant to evidence the contrary.

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As to claim 28, Lunsmann teaches that the benzalkonium chloride is present at a concentration more preferably from about 0.1 to about 0.4 weight percent based on the total weight of the composition (page 2, [0014]).

As to claim 30, Lunsmann teaches that the non-ionic surfactant is present in the amount of 0.1 to 10% by weight and preferably 0.1 to 1% by weight of the composition (page 3, [0020]).

As to claims 31, 57 and 70, Lunsmann teaches in Examples 1 – 6 the use of 1% propylene glycol by weight of the composition (see Table 1).

As to claim 36, Lunsmann teaches that the antimicrobial composition may also comprise chelating agents and preservatives among other agents (page 2, [0015]).

As to claims 53 - 54, Lunsmann teaches that the wipe may comprise wood pulp fibers (page 4, [0031]), which are known in the art to be cellulosic.

As to claims 58 and 71, Lunsmann teaches that the antimicrobial composition may comprise additional materials such as preservatives (page 2, [0015]).

As to claims 27, 34 - 35, 38, 50 – 51, 58 and 71, Lunsmann discloses the claimed invention except for that benzalkonium halide is present in an amount less than 2000 parts per million of the *released* solution as stated in claims 27 and 35, benzalkonium halide is present in the amount of about 150 to about 400 parts per million of *released* solution as stated in claims 34 and 38, benzalkonium halide is present in an amount of less than about 400 parts per million of the *released* solution as stated in claims 50 – 51 and that the preservative is present in the amount of 0.001 – 5 % by weight as required by claims 58 and 71. However, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time

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the invention was made to optimize the amount of benzalkonium halide present in the released solution to an amount less than 2000 parts per million of the *released* solution as stated in claims 27 and 35, benzalkonium halide in the amount of about 150 to about 400 parts per million of *released* solution as stated in claims 34 and 38 and benzalkonium halide in an amount of less than about 400 parts per million of the *released* solution as stated in claims 50 – 51 and that the preservative is present in the amount of 0.001 – 5 % by weight as required by claims 58 and 71, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454 USPQ 233 (CCPA 1955). In the present invention, one would have been motivated to optimize the concentration of benzalkonium halide in the released solution in order to create a wipe with optimal biocidal effectiveness. In the present invention, one would have been motivated to optimize the amount of preservative based on the desired properties.

As to claims 27, 32 – 33, 35, 37, 59 - 68 and 72 – 81, although Lunsman does not explicitly teach the claimed log reduction for E. Coli, S. Aureus or both is at least about 3 and the Kill Efficiency Ratio for E. Coli, S. Aureus, or both is at least about 40 as required by claim 27, the log reduction for E. Coli is at least about 4 as required by claim 32, the log reduction for S. Aureus is at least about 4 as required by claim 33, the wiper has a Kill Efficiency Ratio for E. Coli, S. Aureus, or both of a least 200 as required by claim 27, the pH of the sanitizing formulation is greater than about 8 as required by claims 59 and 72, the pH of the sanitizing formulation is between about 9 and about 12 as required by claims 60 and 73, the log reduction for E. Coli is at least about 3 as required by claims 61 and 74, the log reduction for E. Coli is at

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least about 4 as required by claim 75, the log reduction for E. Coli is at least about 5 as required by claims 62 and 76, the log reduction for S. Aureus is at least about 3 as required by claims 63 and 77, the log reduction for S. Aureus is at least about 4 as required by claim 78, the log reduction for S. Aureus is at least about 5 as required by claims 64 and 79, the Kill Efficiency Ratio for E. Coli, S. Aureus or both is at least about 100 as required by claims 65 and 80, the Kill Efficiency Ratio for E. Coli, S. Aureus or both is at least about 200 as required by claim 66, the Kill Efficiency Ratio for E. Coli, S. Aureus or both is at least about 400 as required by claims 67 and 80 and the wiper exhibits an Antimicrobial Reduction of less than about 95% as required by claim 68, it is reasonable to presume that the properties are inherent to Lunsman. Support for said presumption is found in the use of like materials (i.e. a nonwoven substrate comprising a composition comprising at least one non-ionic surfactant and Applicant's specific benzalkonium halide in Applicant's claimed ranges) which would result in the claimed properties. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties above would obviously have been present once the Lunsman product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

### ***Claim Rejections - 35 USC § 103***

5. Claims 27 - 38 and 50 - 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (US 2002/0103098 A1).

Harrison et al. is directed to a low residue aqueous hard surface cleaning and disinfecting composition (Title).

As to claims 27 and 35, Harrison teaches an aqueous-based cleaning composition comprising a quaternary ammonium surfactant compound having germicidal properties (Abstract). Harrison teaches that the quaternary ammonium compound is present in an amount of from about 0.0025% to about 0.5% wt based on the total weight of the inventive composition (page 2, [0017]). Harrison teaches that the composition may be applied to a hard surface by using a wet wipe comprising a non-woven fabric (page 7, [0091]). The Examiner equates the non-woven fabric to Applicant's "substrate". Harrison teaches the claimed invention except fails to disclose that the quaternary ammonium compound is released from the substrate as a solution during use of the wiper in food service applications. Since the wipe of Harrison meets the structural and chemical limitations set forth by the Applicant and there is nothing on record that shows that the fabric of Harrison cannot be incorporated into a wipe for use in food service applications, it would have been obvious to incorporate the wipe of Harrison into use for a food service application motivated by the desire to expand the range of uses for the wipe.

As to claim 28, Harrison teaches that the quaternary ammonium compound is present in an amount of from about 0.0025% to about 0.5% wt based on the total weight of the inventive composition (page 2, [0017]).

As to claim 29, Harrison teaches that a chelating agent may be present in the formulation (page 4, [0056]). It should be noted that it is known in the art that a chelating agent is a sequestrant. Harrison teaches that the chelating agent may be present in amounts less than 2.5% by weight of the composition (page 5, [0056]).

As to claim 30, Harrison teaches that the composition may contain a nonionic surfactant (page 4, [0056]). Harrison teaches that the nonionic surfactant is present in amounts less



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than 2.5% by weight of the composition (page 5, [0056]).

As to claims 31, 57 and 70, Harrison teaches that the composition comprises an alkylene glycol solvent such as propylene glycol n-butyl (pages 3 and 4, [0046]). It should be noted that on page 23, lines 20 – 30 of the Applicant's Specification, the Applicant indicates that propylene glycol is a non-aqueous solvent. Harrison teaches that the propylene glycol n-butyl is present in amount ranging from 0.01% to 10% wt (page 4, [0046]).

As to claim 36, Harrison teaches that the composition may comprise chelating agents (page 5, [0057]).

As to claims 53 – 54, Harrison teaches that the wipe can comprise wood pulp fibers (page 7, [0092]) which are known in the art to be cellulosic.

As to claims 56 and 69, Harrison teaches that BARDAC 2080 may be used as the quaternary ammonium compound (page 2, [00166]). It should be noted that on page 14, line 23 of Applicant's Specification, the Applicant indicates that BARDAC 2080 meets the requirements of the formula in claim 3.

As to claims 27, 34 - 35, 38 and 50 - 51, Harrison discloses the claimed invention except for that benzalkonium halide is present in an amount less than 2000 parts per million of the *released* solution as stated in claims 27 and 35, benzalkonium halide is present in the amount of about 150 to about 400 parts per million of *released* solution as stated in claims 34 and 38 and benzalkonium halide is present in an amount of less than about 400 parts per million of the *released* solution as stated in claims 50 - 51. Also, as to claims 27 and 35, Harrison discloses the claimed invention except for that the sanitizing formulation is present in the substrate in an

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amount from about 150 – 600% of the dry weight of the wiper. However, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the amount of benzalkonium halide present in the released solution to an amount less than 2000 parts per million of the *released* solution as stated in claims 27 and 35, benzalkonium halide in the amount of about 150 to about 400 parts per million of *released* solution as stated in claims 34 and 38, benzalkonium halide in an amount of less than about 400 parts per million of the *released* solution as stated in claims 50 – 51 and it would have been obvious to optimize the amount of sanitizing formulation present in the substrate to an amount from about 150 – 600% of dry weight of the wiper, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454 USPQ 233 (CCPA 1955). In the present invention, one would have been motivated to optimize the concentration of benzalkonium halide in the released solution in order to create a wipe with optimal biocidal effectiveness. In the present invention, one would have been motivated to optimize the level of sanitizing formulation based on the dry weight of the wiper in order to effectively and efficiently clean the desired surface.

As to claims 27, 32 – 33, 35, 37, 59 – 68 and 72 – 81, although Harrison does not explicitly teach the claimed log reduction for E. Coli, S. Aureus or both is at least about 3 and the Kill Efficiency Ratio for E. Coli, S. Aureus, or both is at least about 40 as required by claim 27, the log reduction for E. Coli is at least about 4 as required by claim 32, the log reduction for S. Aureus is at least about 4 as required by claim 33, the wiper has a Kill Efficiency Ratio for E.

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Coli, S. Aureus, or both of a least 200 as required by claim 27, the pH of the sanitizing formulation is greater than about 8 as required by claims 59 and 72, the pH of the sanitizing formulation is between about 9 and about 12 as required by claims 60 and 73, the log reduction for E. Coli is at least about 3 as required by claims 61 and 74, the log reduction for E. Coli is at least about 4 as required by claim 75, the log reduction for E. Coli is at least about 5 as required by claims 62 and 76, the log reduction for S. Aureus is at least about 3 as required by claims 63 and 77, the log reduction for S. Aureus is at least about 4 as required by claim 78, the log reduction for S. Aureus is at least about 5 as required by claims 64 and 79, the Kill Efficiency Ratio for E. Coli, S. Aureus or both is a least about 100 as required by claims 65 and 80, the Kill Efficiency Ratio for E. Coli, S. Aureus or both is least about 200 as required by claim 66, the Kill Efficiency Ratio for E. Coli, S. Aureus or both is at least about 400 as required by claims 67 and 80 and the wiper exhibits an Antimicrobial Reduction of less than about 95% as required by claim 68, it is reasonable to presume that the properties are inherent to Harrison. Support for said presumption is found in the use of like materials (i.e. a nonwoven substrate comprising a composition comprising at least one non-ionic surfactant and Applicant's specific benzalkonium halide in Applicant's claimed ranges) which would result in the claimed properties. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties above would obviously have been present once the Harrison product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

***Response to Arguments***

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6. Applicant's arguments filed September 2, 2005 have been fully considered but they are not persuasive.

Applicant argues that Harrison does not recognize that it may be beneficial to know the contents of the solution the wiper is releasing – more particularly, to know and to control, the benzalkonium halide content within that release solution. It should be noted that “The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art for all they contain”. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). See MPEP 2123. Although Harrison may not be concerned with the amount of benzalkonium halide content in the released solution, a certain amount of benzalkonium would be released upon use depending on various factors. Absent unexpected results, the Examiner submits it would be obvious to optimize the amount of benzalkonium halide content in the released solution motivated by the desire to create a wipe with optimal biocidal effectiveness.

Applicant argues that Harrison requires the use of carboxylate or N-acyl amino acid surfactant, which are “anionic” surfactants, which are specifically excluded from independent claims 27 and 35. It should be noted that Applicant has not set forth the basic and novel characteristics of the sanitizing formulation and has failed to demonstrate how the inclusion of anionic surfactant would affect the basic and novel characteristics. Absent this showing, the Examiner continues to interpret the transitional phrase “consisting essentially of” as “comprising”. It should be noted that “comprising” is open language and does not exclude any

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additional unrecited components. Please refer to the Examiner's response to Arguments in the previous Office Action, paragraph 7.

Applicant argues that Harrison does not teach the Kill Efficiency Ratio of at least about 40 as now required by claims 27 and 35. Applicant indicates that the ratio greatly depends on the selected combination of features (e.g., the ingredients of the formulation, relative amounts, add-on levels, wiper materials, etc.). Since Harrison meets each and every chemical and structural requirement for the wiper containing the sanitizing formulation set forth in the claims, the wiper must meet Kill Efficiency Ratio that depends from said requirements. Since no other structural or chemical features are claimed in the independent claims, which may distinguish the present invention from Harrison, the presently claimed Kill Efficiency Ratio is deemed to be inherent to Harrison. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 495. Without a showing that evidences a difference between Harrison and the present invention, anticipation is proper. However, such evidence could support the proposition that the current claims are incomplete. Given that the applied art desires and is designed to function as Applicant's intend their invention to function in all comparable aspects, including same utility, one can only conclude that Harrison inherently possesses the required Kill Efficiency Ratio (along with the other properties), absent some evidence or showing that such a conclusion does not follow from the facts of record. The Examiner believes passing to issue such claims that appear to be encompassed by Harrison or are unclear as to what would infringe, would be an error on the part of the Office.

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***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cheung et al. (US 6,136,770) is directed to hard surfacing cleaning and disinfecting compositions containing Applicant's main chemical components and can be applied to a nonwoven wiper.

Sherry et al. (US 6,716,805) is directed to a hard surface cleaning composition and a premoistened wiper comprising Applicant's main chemical components.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jennifer Boyd

November 18, 2005

  
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